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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,932	09/08/2000	Nobutaka Wakamiya	19036/36615	2688

7590

10/03/2002

David A Gass  
Marshall O'Toole Gerstein Murray & Borun  
6300 Sears Tower  
233 South Wacker Drive  
Chicago, IL 60606-6402

EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 10/03/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/600,932	WAKAMIYA, NOBUTAKA09600932	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2000.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,7,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6&amp;7</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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**DETAILED ACTION**

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of invention, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I      Claims 1, 2, 5, 6, 8 and 9 drawn to a polynucleotide comprising the nucleotide sequence set forth in SEQ ID NO: 1, which encodes a protein having the amino acid sequence set forth in SEQ ID NO: 2, wherein the polynucleotide which can hybridize with the polynucleotide of claim 2, wherein the protein encoded by said polynucleotide comprises (1) a Ca<sup>2+</sup> dependent carbohydrate recognition domain (CRD), (2) a neck region, (3) a collagen like region, and (4) an N-terminal region containing cysteine, a collectin protein comprising the amino acid sequence of SEQ ID NO: 2 encoded by the polynucleotide comprising the nucleotide sequence of SEQ ID NO: 1; classified in class 536, subclass 23.5; class 530, subclass 395, 396

Group II      Claims 3, 4, 7, 10 and 11, drawn to a polynucleotide sequence which encodes a collectin protein, wherein said polynucleotide can hybridize under stringent condition with a probe produced from a genomic clone which shares homology to a consensus collectin amino acid sequence set forth in SEQ ID NO: 3, wherein the

Art Unit: 1653

the probe is generated by PCR using primers having nucleotide sequence set forth in SEQ ID NO: 7 and SEQ ID NO: 8, a collectin protein encoded by the polynucleotide of claim 3, wherein the the collectin protein is derived from human, wherein the amino acid sequence of the collectin protein polypeptide comprises deletion, substitution and/or addition of one or more amino acids of the collectin protein, and wherein the protein comprises: (1) a  $\text{Ca}^{2+}$  dependent carbohydrate recognition domain (CRD), (2) a neck region, (3) a collagen like region, and (4) an N-terminal region containing cysteine; classified in class 536, subclass 23.5, 24.3, 24.33; class 435, subclass 91.2; class 530, subclasses 395, 396.

The claims of these groups are directed to different inventions, which are not linked to form a single general concept. The claims in the different groups do not have in common the same or corresponding technical features. In particular, each group is directed to distinct chemical entities and/or methods, which use different materials and produce different effects. Accordingly, the claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept and lack of unity is deemed proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1653

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

During a telephone conversation with Attorney David Gass on June 26, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1, 2, 5, 6, 8 and 9. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 4, 7, 10 and 11 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, claims 1, 2, 5, 6, 8 and 9 are currently pending and are under examination.

#### ***Priority***

Applicant's claim for foreign priority under 35 U.S.C. 119 (a-d) is acknowledged. This application is a 371 of PCT/JP98/03328 filed on July 24, 1998 which claims a priority of a Japanese Application No. 10-11281, filed on January 23, 1998. However, the instant application fails to provide a copy of the certified English translations in support of the priority date claimed. Therefore, the priority date granted is July 24, 1998.

#### ***Information Disclosure Statement***

The information disclosure statement filed November 13, 2000 and the supplemental IDS filed May 10, 2001 is acknowledged. A copy of an English translation of the Japanese references B2, C4, C13, C23 and C26 (paper #6) reference was not submitted. The statement in paper #7 indicates that a patent listed in 1449 is submitted. Therefore, PTO-1449 in paper #6 and in paper #7 have been placed in the application file and considered with regard to the references which have been submitted. Note that references which have not been supplied with this application have been lined through. Consideration of the lined through reference will be made upon compliance with 37CFR 1.98 .

#### ***Objection to Specification***

Art Unit: 1653

The disclosure is objected to for the following informality:

This application is a 371 of PCT/JP98/03328 filed on July 24, 1998 which claims a foreign priority benefits of a Japanese Application No. 10-11281, under 35, U.S.C, Section 119(a)-(d) filed on January 23, 1998 and the continuing data is not entered in the first page, first line of the specification. An appropriate correction is required.

***Claim Rejection, 35 U.S.C. 101, Non-Statutory***

Claims 1, 2 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. "A polynucleotide" is a non-statutory subject matter (claims 1, 2). The claim should read as "an isolated polynucleotide." Claim 8 reads as "A collectin protein", that renders the claim non-statutory subject matter, a correction to read the claim as "An isolated collectin protein" would overcome this rejection.

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5, 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 drawn to a polynucleotide comprising the nucleotide sequence which encodes a protein having the amino acid sequence of SEQ ID NO: 2. Claim 2 is drawn to a polynucleotide comprising the nucleotides sequence of SEQ ID NO: 1. It is clear from the specification that Applicants were in possession of the said sequences at the time the invention was made. Claim 5 encompasses the subject matter that is not defined in the specification. The claim is directed to a

Art Unit: 1653

polynucleotide which can hybridize with the polynucleotide of claim 2, wherein the protein encoded by said polynucleotide comprises 1) a  $\text{Ca}^{2+}$  dependent carbohydrate recognition domain (CRD), 2) a neck region, 3) a collagen-like region and 4) an N-terminal region containing cysteine. However, Applicants have given no concise definition of the terms listed in 1-4. The specification indicates at page 3, lines 21-25 that the polynucleotide which can hybridize with any of the polynucleotide according to claim 1, or claim 2 or a polynucleotide which encodes a collectin protein, wherein the protein encoded by said polynucleotide comprises 1) a  $\text{Ca}^{2+}$  dependent carbohydrate recognition domain (CRD), 2) a neck region, 3) a collagen-like region and 4) an N-terminal region containing cysteine. However, no guidance is provided to determine what are those polynucleotides, which can hybridize with the polynucleotides that encodes a protein that comprises a CRD domain, a neck region, a collagen-like region and an N-terminal region containing cysteine. There is no description of the function of these polynucleotides and the protein encoded by them and the structural information is also limited. Therefore, there is lack of written description as to what are those polynucleotides and the polypeptides encoded by them, which have some activity related to the activity of collectin protein.

Claims 1, 2, 5, 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claim 5, the specification does not enable the skilled artisan to use the claimed invention because the specification fails to provide a written description of a polynucleotide that encodes a protein having a 1) CRD domain, 2) a neck region, 3) a collagen-like region and 4) an N-terminal region containing cysteine, which hybridizes with polynucleotide of SEQ ID NO: 1. No guidance is provided for how to use them to practice the invention. Claim 8 is assumed to have been a method of treating claim. The scope of said claim is vastly in excess of the single embodiment provided in page 6-7 of the instant disclosure. Without additional test data, extrapolation beyond that example is not adequately supported at present.

Art Unit: 1653

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

“The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”

Claims 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is indefinite because of the use of the term “hybridize” is not clear. Recitation of the stringent hybridization condition in the claim will overcome this rejection.

Claim 5 is indefinite because the first part of the claim requires polynucleotide to hybridize with the polynucleotide of claim 2 and second part of the claim requires the said polynucleotide to encode a protein of claim 2. If the polynucleotide of claim 5 is a non-coding strand then it hybridizes with the complement that is coding strand of the polynucleotide of claim 5. If the coding strand of claim 5 encodes the same protein of claim 2, then it cannot hybridize with the polynucleotide of claim 5.

***Conclusion***

No claims are allowed.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology



Application/Control Number: 09/600,932

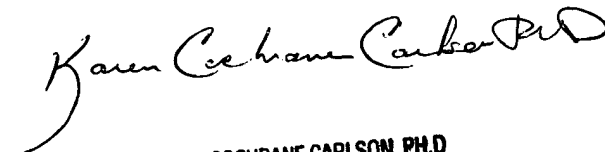
Page 8

Art Unit: 1653

Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.  
September 21, 2002



KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER